

Package leaflet: Information for the patient
Depo-Medrone® 40 mg/ml Injection
(methylprednisolone acetate)

Your medicine is known as the above but will be referred to as Depo-Medrone throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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- 1. What Depo-Medrone is and what it is used for**

Depo-Medrone contains methylprednisolone acetate.

Methylprednisolone belongs to a group of medicines called corticosteroids or steroids. Corticosteroids are produced naturally in your body and are important for many body functions.

Boosting your body with extra corticosteroid such as Depo-Medrone can help when injected into the body by a doctor or nurse, such as in or near a joint, to treat local symptoms caused by inflammatory or rheumatic conditions such as:

- **Bursitis:** inflammation in the fluid containing spaces around the shoulder, knee and/or elbow joints. For this condition this medicine will be injected directly into one or more of these spaces.

- **Osteoarthritis and rheumatoid arthritis:** inflammation located in between the joints. For these conditions this medicine will be injected directly into one or more joint spaces.

- **Plantar fasciitis:** inflammation of the tissues of the sole of the foot.
- **Skin problems:** such as alopecia areata (patchy baldness), keloids (scar tissue), lichen planus or simplex (small, purplish raised patches of skin or spots), discoid lupus (round-shaped patches, often on the face) or granuloma annulare (circular warty growths).
- **Epicondylitis (tennis elbow) and tenosynovitis:** For these conditions this medicine will be injected into the tendon sheath.

Alternatively this medicine may be injected into a muscle to help treat more general (systemic) problems affecting the whole body (e.g. symptoms caused by a hypersensitivity to a medicine), or allergic, inflammatory or rheumatic problems affecting the:

- **brain** e.g. meningitis caused by tuberculosis
- **bowel and gut** e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel)
- **joints** e.g. rheumatoid arthritis
- **lungs** e.g. asthma, tuberculosis or inflammation caused by breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson syndrome (an autoimmune disorder in which an immune system causes the skin to blister and peel) or systemic lupus erythematosus (lupus).

Your doctor may use this medicine to treat conditions other than those listed above. Ask your doctor if you are unsure why you have been given this medicine.

- 2. What you need to know before you are given Depo-Medrone**

Do not use Depo-Medrone if:

- You think you have ever suffered an **allergic** reaction, or any other type of reaction after being given Depo-Medrone, or any other medicine containing a corticosteroid or any of the ingredients in this medicine (listed in section 6).

An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.

- You get a **rash**, or another symptom of an infection.
- You have recently had, or are about to have any **vaccination**.

See your doctor immediately if any of the above applies to you.

Do not inject this medicine:

- into the **Achilles tendon** (which is located behind the ankle joint), or
- directly into a **vein (intravenous)**, the spinal cord (intrathecal), the outer covering of the brain (extradural), into the nostrils (intranasal) or in the eye (intraocular).

Warnings and precautions

Talk to your doctor or nurse before taking Depo-Medrone if you have any of the following conditions.

Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

- **Acute adrenal insufficiency** (when your body cannot produce enough corticosteroid due to problems with your adrenal glands).
- **Acute pancreatitis** (inflammation of the pancreas).
- **Chickenpox, measles, shingles** or a **herpes** eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Depo-Medrone, or having a family history of these illnesses.
- **Cushing's disease** (condition caused by an excess of cortisol hormone in your body).
- **Diabetes** (or if there is a family history of diabetes).
- **Epilepsy, fits or seizures**.
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- Contact your doctor if you experience **blurred vision or other visual disturbances**.
- You have recently suffered a **heart attack**.
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure).
- **Hypotension** (low blood pressure).

- **Hypothyroidism** (an under-active thyroid).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Joint infection**.
- **Kidney** or **liver** disease.
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (muscle disease with muscle fatigue), or if during treatment you develop muscular disorders.

- **Osteoporosis** (brittle bones).
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis may be increased. Signs of scleroderma renal crisis include raised blood pressure and decreased urine production.

- **Skin abscess**.
- **Stomach ulcer** or other serious stomach or intestinal problems.
- Unusual **stress**.
- **Thrombophlebitis** - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Tuberculosis** (TB) or if you have suffered tuberculosis in the past.
- **Traumatic brain injury**.

Depo-Medrone treatment may increase your risk of infection, may mask some signs of infections, make current infections worse, or cause old, hidden infections to come back or get worse. New infections may also appear during Depo-Medrone use. Different infections may therefore occur more easily during the treatment. Please report any signs or symptoms of infection to your doctor or nurse. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

Tumour lysis syndrome can occur after treatment of a fast-growing cancer, especially certain leukemias and lymphomas (cancers of the blood) or solid tumours. As the tumour cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood, which may cause damage to organs, including the kidneys, heart and liver that may lead to muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Contact your doctor immediately, if you experience any muscle pain, muscle weakness, and /or red-brown change in the colour of your urine as this might be a sign of rhabdomyolysis which is a severe condition involving breakdown of your muscles.

You **must** tell your doctor before you take this medicine if you have any of the conditions listed above.

Other medicines and Depo-Medrone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following medicines which can affect the way Depo-Medrone or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Aminoglutethimide** and **cyclophosphamide** – used for treating cancer.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).

- **Oral Anticoagulants** of the vitamin K antagonists class – used to prevent blood clotting such as acenocoumarol, phenindione, fluindione and warfarin.
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine.
- **Antidiabetics** – medicines used to treat high blood sugar.
- **Antiemetics** (such as aprepitant and fosaprepitant).
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- **Aspirin** and non-steroidal anti-inflammatory medicines (also called **NSAIDs**) such as ibuprofen used to treat mild to moderate pain.
- **Barbiturates, carbamazepine, phenytoin and primidone** – used to treat epilepsy.
- **Carbenoxolone** - used for heartburn and acid indigestion.
- **Ciclosporin** - used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.

- **Digoxin** - used for heart failure and/or an irregular heart beat.
- **Diltiazem** – used for heart problems or high blood pressure.
- **Ethinylestradiol** and **norethindrone** – oral contraceptives.
- **Ketoconazole** or **itraconazole** – used to treat fungal infections.
- **Pancuronium, vecuronium** – or other muscle relaxants called neuromuscular blocking agents which are used in some surgical procedures.
- Potassium depleting agents – such as **diuretics** (sometimes called water tablets), **amphotericin B**, **xanthenes** or **beta2 agonists** (e.g. medicines used to treat asthma).

- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB).
- **Tacrolimus** – used following an organ transplant to prevent rejection of the organ.
- **Vaccines** - tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **must not** have 'live' vaccines while using this medicine. Other vaccines may be less effective.

If you are taking long term medication(s)

If you are being treated for diabetes, high blood pressure or water retention (oedema) tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operation tell your doctor, dentist or anaesthetist that you are taking this medicine.

If you require a test to be carried out by your doctor or in hospital it is important that you tell the doctor or nurse that you are taking Depo-Medrone. This medicine can affect the results of some tests.

Depo-Medrone with drink

Do not drink grapefruit juice while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as this medicine could slow the baby's growth. There is a risk associated with low birth weight of the baby; this risk can be reduced by administering a lower dose of the medicine.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine, as small amounts of corticosteroid medicines may get into breast milk.

If you continue breast-feeding while you are having treatment, your baby will need extra checks to make sure he or she is not being affected by your medicine.

Driving and using machines

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected do not drive or operate machinery.

Depo-Medrone contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

- 3. How Depo-Medrone is given to you**

Steroid Cards

Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist has filled out the details of your medicine, including the dose and how long you will require steroid treatment.

You should show your steroid card to **anyone** who gives you treatment (such as a doctor, nurse or dentist) while you are taking this medicine, and for 3 months after your last injection.

If you are admitted to hospital for any reason always tell your doctor or nurse that you are taking this medicine. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

Dosage information

Your doctor will decide on the site of injection, how much of the medicine and how many injections you will receive depending on the condition being treated and its severity. Your doctor will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

Adults

Your doctor/nurse will tell you how many injections you will require for the condition you are being treated for, and when you will get them.

Joints - the normal dose for the injections into joint will depend on the size of the joint. Large joints (e.g. knee, ankle and shoulder) may require 20 – 80 mg (0.5 – 2 ml), medium sized joints (e.g. elbow or wrist) 10 – 40 mg (0.25 – 1 ml) and small joints (e.g. finger or toe joints) may require a 4 – 10 mg (0.1 – 0.25 ml) dose. Joint injections may be given weekly over a period of several weeks, depending on how quickly you respond to treatment.

Bursitis and epicondylitis (tennis elbow) – the usual dose is between 4 – 30 mg (0.1 – 0.75 ml). In most cases repeat injections will not be needed for bursitis and epicondylitis. Repeat injections may be necessary to treat long standing conditions.

The following information is intended for healthcare professionals only:

FOR FURTHER INFORMATION PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

Posology and method of administration

Depo-Medrone should not be mixed with any other suspending agent or solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever suspension and container permit. Depo-Medrone may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional and into the tendon sheath. It must not be used by the intrathecal or intravenous routes.

Undesirable effects may be minimized by using the lowest effective dose for the minimum period (see special warnings and precautions section in SPC).

Depo-Medrone vials are intended for single dose use only.

Adults

Intramuscular – for sustained systemic effect: Allergic conditions (asthma, drug reactions). 80 – 120 mg (2 – 3 ml).

Dermatological conditions, 40 – 120 mg (1 – 3 ml).

Rheumatic disorders and collagen diseases (rheumatoid arthritis, SLE), 40 – 120 mg (1 – 3 ml) per week.

Dosage must be individualised and depends on the condition being treated and its severity.

The frequency of intramuscular injections should be determined by the duration of the clinical response.

On average the effect of a single 2 ml (80 mg) injection may be expected to last approximately two weeks.

Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Depo-Medrone depends upon the size of the joint and the severity of the condition. Repeated injections, if needed, may be given at intervals of one to five or more weeks depending upon the degree of relief obtained from the initial injection.

A suggested dosage guide is: large joint (knee, ankle, shoulder), 20 – 80 mg (0.5 – 2 ml); medium joint (elbow, wrist), 10 – 40 mg (0.25 – 1 ml); small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 4 – 10 mg (0.1 – 0.25 ml).

Intrabursal: Subdeltoid bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 4 – 30 mg (0.1 – 0.75 ml). In most cases, repeat injections are not needed.

Intralesional: Keloids, localized lichen planus, localized lichen simplex, granuloma annulare, alopecia areata, and discoid lupus erythematosus. For administration directly into the lesion for local effect in dermatological conditions, 20 – 60 mg (0.5 – 1.5 ml). For large lesions, the dose may be distributed by repeated local injections of 20 – 40 mg (0.5 – 1 ml). One to four injections are usually employed. Care should be taken to avoid injection of sufficient material to cause blanching, since this may be followed by a small slough.

Periarticular: Epicondylitis. Infiltrate 4 – 30 mg (0.1 – 0.75 ml) into the affected area.

Into the tendon sheath: Tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 4 – 30 mg (0.1 – 0.75 ml). In recurrent or chronic conditions, repeat injections may be necessary.

Special precautions should be observed when administering Depo-Medrone. Intramuscular injections should be made deeply into the gluteal muscles. The usual technique of aspirating prior to injection should be employed to avoid intravascular administration. Doses recommended for intramuscular injection must not be administered superficially or subcutaneously.

